

## REMARKS

Claims 22-26, 28-33, 36-50, 52-87 and 90-94 are pending. Of these, claims 66-73, 91 and 92 have been withdrawn from consideration. Claims 22-26, 28-33, 36-50, 52-65, 74-87, 90, 93 and 94 are rejected. Claims 22, 39, 42, 68, 69 and 90 have been amended. Claim 46 has been canceled without prejudice or disclaimer. New claim 95 has been added. Reconsideration of the rejection is respectfully requested in view of the following remarks.

Applicants respectfully submit that the instant claim amendments are fully supported by the specification as originally filed. In particular, support for the claimed pressure applied "of at least 0.2 ton per square inch" can be found in, for instance, in the paragraph bridging pages 14 and 15. Moreover, support for the claim limitation about the fibers "not being cross-linked" also can be found in this same paragraph. Further, the limitation in claim 42 about the fiber orientation in a plate being independent of the orientation of fibers in adjacent plates finds support in former claim 46.

By way of a brief review, the instant invention pertains to a prosthetic device containing fibers that are at least partially aligned. Prosthetic devices can be used in the repair, augmentation or replacement of diseased or damaged organs such as muscles (e.g., rotator cuff injuries), intervertebral disc, ligaments, or defects in the *dura mater* or abdominal wall, among other applications. The fibrous prosthetic devices of the present invention are structurally stable, pliable, suturable, and can be made porous or non-porous.

Among the many limitations regarding the composition or structural arrangement of materials making up the claimed device are:

- (i) that the device comprises at least partially aligned polymer fibers;
- (ii) that the fibers organize themselves into plates of aligned fibers;
- (iii) that there is space between adjacent plates called "fluid planes";
- (iv) that the fluid planes exist as multiple fissures; and
- (v) that the fissures arrange themselves randomly throughout the structure of the device.

In an excess of caution, Applicants direct the Examiner's attention to the fact that not all of these limitations are found in every independent claim.

The claimed prosthetic device is fabricated using unique processing. The instant specification explains that this processing of the instant invention gives rise to unique characteristics, for example, that the alignment of the fibers manifests itself as plates or layers of aligned fibers, and the production of implant devices that do not require freezing or cross-linking to impart sufficient strength to permit handling.

### **Claim Rejections – 35 USC §112**

Claims 22, 31, 39, 42 and 66 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

The Action states that it could not find support in the specification as originally filed for the new limitations within claims 22, 31 and 42 to the effect that the mixture is not constrained lateral to the compression direction. Applicants respectfully submit that the instant amendments of claims 22, 31 and 42 render this rejection moot with respect to these specific claims. As for dependent claim 93 and new claim 95, Applicants respectfully submit that Figures 2E and 3A-3B inherently show the absence of constraint in directions lateral to the compression direction. Figures 3A and 3B in particular show the amorphous mass of fibrous dough spreading out lateral to the compression direction. See also page 22, lines 25-28.

Similarly, the Action stated that it could not find support in the specification as originally filed for the new limitations within claims 39 and 66 to the effect that the compressing force is exclusive of any rotation from a piston or mold. Applicants respectfully submit that support for this particular language is inherent in the specification as a whole and as originally filed, as there is nothing in the specification that discloses or suggests such rotation of a piston or a mold. Further support for Applicants' position that the language at issue is inherently present in the application as originally filed comes from the attached Declaration of co-inventor Timothy Ringeisen. Accordingly, Applicants have amended the instant specification to expressly recite this **inherent feature of the instant invention**.

Thus, the new language in the claims is inherently supported by the original specification, as explained in part using the language of the co-inventor's Declaration. Accordingly, this rejection should be withdrawn.

### **Election by Original Presentation**

Applicants acknowledge the examiner's withdrawal of the previous withdrawal of claim 90.

### **Claim Rejections – 35 USC §102/103**

Claims 22-26, 28-33, 38-45, 47-49, 52-53, 61-65, 74-77, 80-81, 84, 87, 90 and 92-93 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,158,574 to Stone (hereinafter referred to as "Stone"). Claims 22-26, 28-30, 36-48, 52-65, 74-84, 87, 90 and 92-93 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Publication No. US2002/0127270 to Li (hereinafter referred to as "Li"). Claims 22-26, 28-33, 36-50, 52-65, 74-87, 90 and 93-94 are rejected under 35 U.S.C. §103(a) as being unpatentable over Stone in view of Li and further in view of U.S. Patent No. 6,428,576 B1 to Haldimann. Applicants respectfully traverse these rejections.

Referring again to the telephonic interview of January 3, 2008, the examiner stated that he would like to see experimental evidence that the Stone and Li structures really *are* different from that of the claimed device. In response, Applicants now attach as Appendices A and B, respectively, scanning electron photomicrographs of cross-sections of the material of the Li Patent and that of the instant invention. The thin white bar in the photo of Appendix A indicates the length of 98 microns in the photo. The corresponding thick white bar in the photos of Appendix B indicates the length of 100 microns. Thus, the "C" SEM photo of Applicants is of roughly the same magnification as the SEM photo of the Li material. One can see that, in the Li material, the plates of material extend uninterrupted across the field of view of the photo. Also, the spaces, fissures or fluid planes between the plates also extend uninterrupted from one side of the photo to the other. In stark contrast, the plates in Applicants' product do not extend all the way across, but are interrupted by the fissures. Furthermore, Applicants' fissures are not neatly organized like the fissures in Li and do not extend completely across the field of view. Instead, Applicants' fissures are randomly located in the product, are interrupted, and are of a random or at least non-uniform shape. Comparing the SEM photos show that the respective products are clearly different.

Regarding all independent claims except 39 and 42: Applicants respectfully submit that none of Stone, Li or Haldimann discloses or suggests the claimed plurality of plates of at least partially aligned fibers defining at least one space therebetween comprising fluid planes, the fluid planes existing as multiple fissures located randomly within the structure of the device.

With further regard to independent claim 31: Applicants respectfully submit that none of Stone, Li or Haldimann discloses or suggests the **location-specific cross-linking** of fibers. More specifically, the references do not disclose or suggest *fibers on the periphery of the device that are at least partially cross-linked, whereas fibers located away from the periphery are not cross-linked*.

With further regard to independent claims 39 and 90: Applicants respectfully submit that none of Stone, Li or Haldimann discloses or suggests the claimed implantable device that is not cross-linked. Applicants respectfully submit that the Stone implant is cross-linked (see col. 4, lines 16-26), as is the device of Li (see Paragraph [0006]).

With further regard to independent claim 42: Applicants respectfully submit that none of Stone, Li or Haldimann discloses or suggests the claimed orientation of fibers within each plate being independent of the orientation of fibers within adjacent plates. The Action argues that Li discloses conscious orientation (presumably referring to Li's laminating embodiment), but that this step is not mandatory, and thus in the absence of a conscious and deliberate orientation of the fiber membranes, the membranes would essentially be random as to their orientation of the alignment of fibers. Applicants respectfully traverse this characterization of Li. Applicants respectfully submit that, in the absence of conscious and deliberate laminating, the sheet membrane Li produces is a single-layer of oriented fibers, "oriented" meaning that at least half the fibers are in one general direction. See Paragraphs [0004] – [0006].

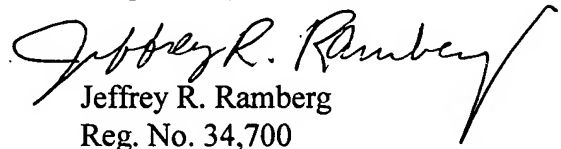
With further regard to independent claims 22 and 42: Each of Stone, Li or Haldimann fails to disclose or suggest the claimed fabrication step of applying a compressive force at a pressure of at least about 0.2 ton per square inch. The specification, for example, at the paragraph bridging pages 14 and 15 states that this pressure is higher than that applied in state-of-the-art devices for extracting fluid and concentrating the fibers, and further that these existing methods do not induce fiber migration or layer formation. In other words, *the instant specification states that prior art methods do not give rise to the arrangement of the fibers of the devices of the instant invention.*

Accordingly, this rejection should be withdrawn.

In view of the amendments and the above remarks, Applicants respectfully submit that the instant application is in condition for allowance. Accordingly, Applicants respectfully request issuance of a Notice of Allowance directed to claims 22-26, 28-33, 36-45, 47-50, 52-65, 74-87, 90 and 93-95.

Should the Examiner deem that any further action on the part of Applicants would be desirable, the Examiner is invited to telephone Applicants' undersigned representative.

Respectfully submitted,

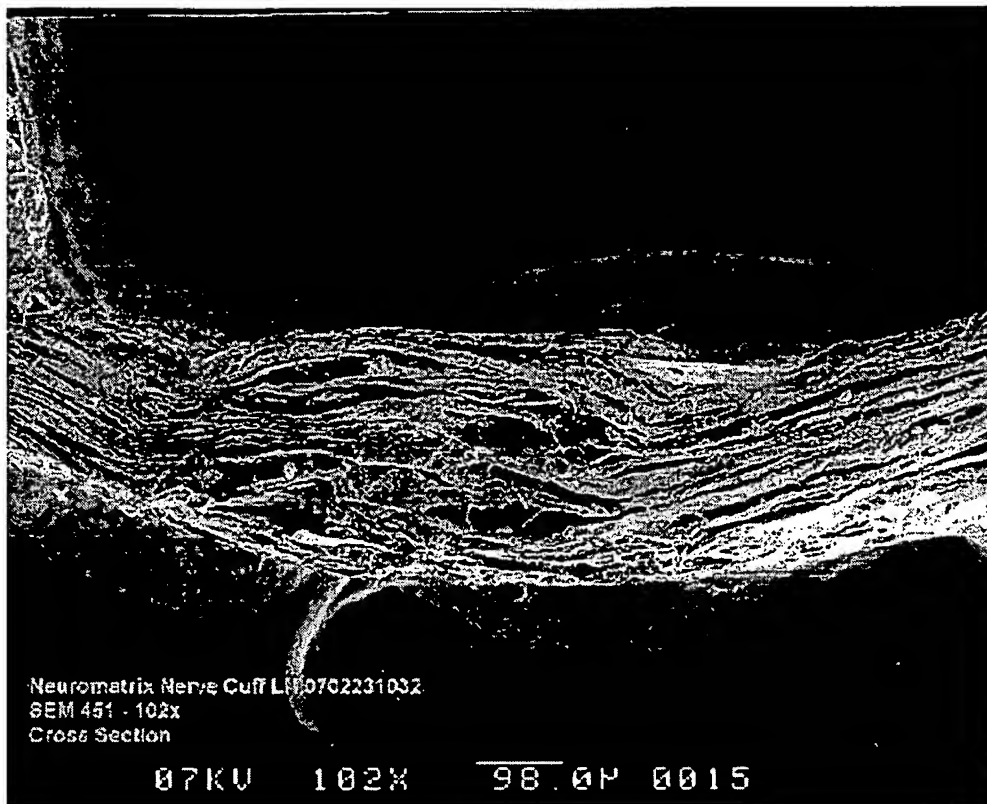
  
Jeffrey R. Ramberg  
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September 9, 2008

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Enclosures:

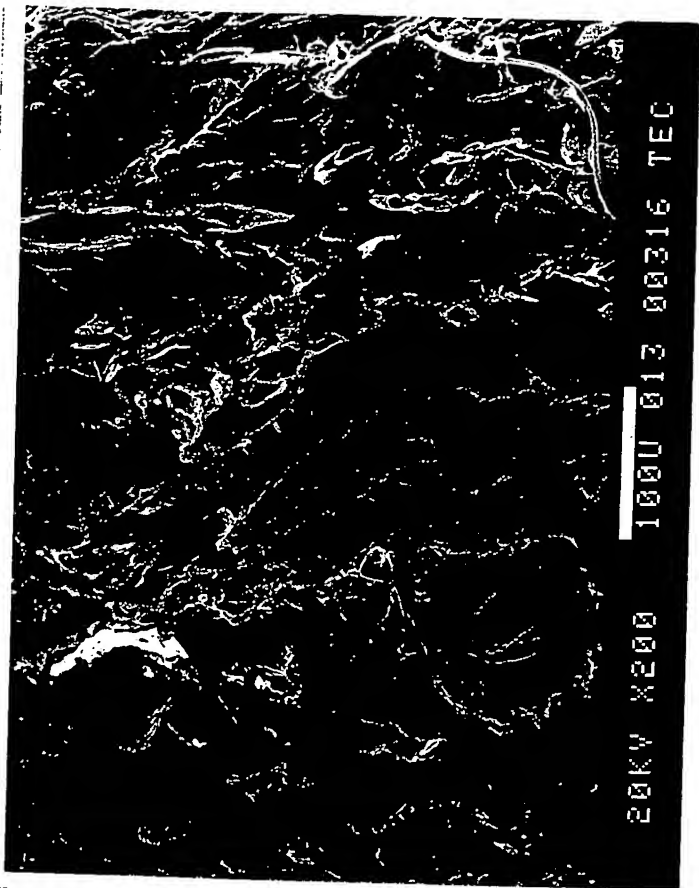
- Appendix A: SEM photomicrograph of cross-section of material made in accordance with the Li Patent
- Appendix B: SEM photomicrograph of material made in accordance with the instant invention
- Appendix C: Declaration under 37 CFR 1.132 of co-inventor Timothy A. Ringeisen



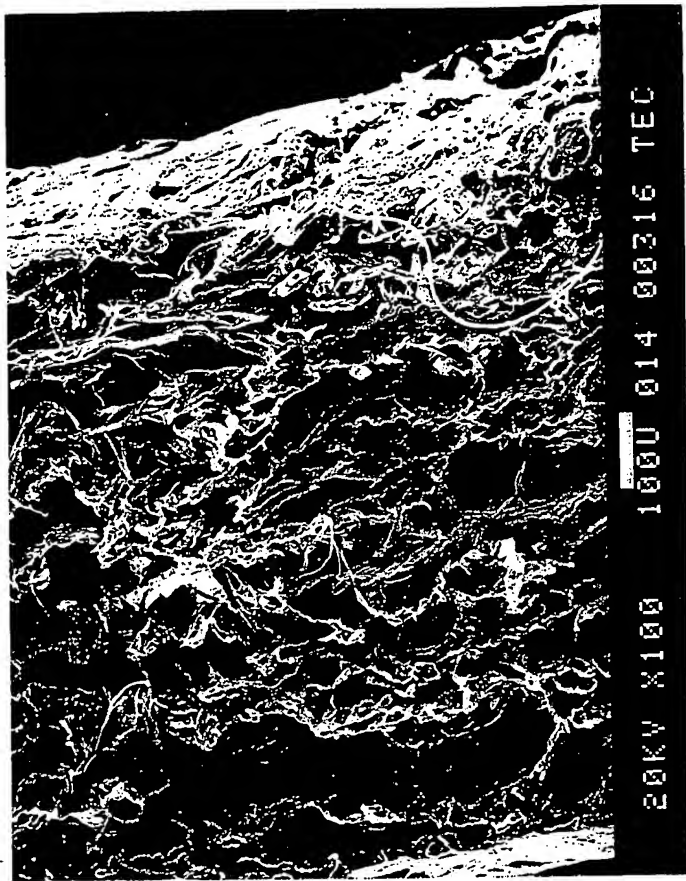
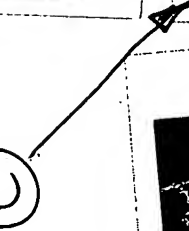
Appendix A

Appendix B

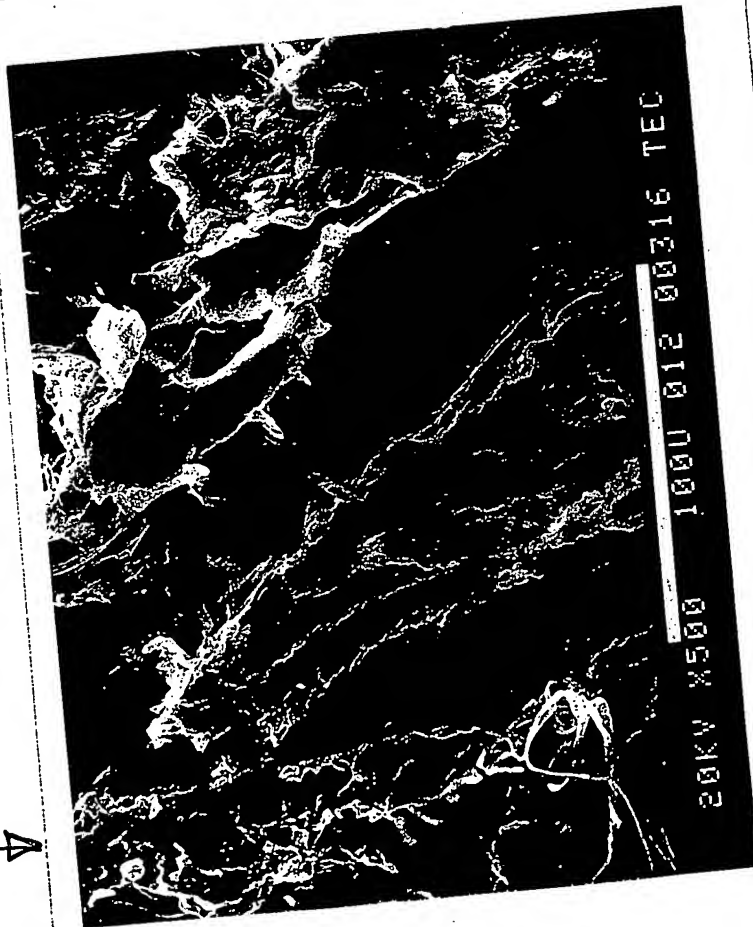
(B)



(C)



(A)



## APPENDIX C

### DECLARATION OF BIOMATERIALS ENGINEER AND CO-INVENTOR TIMOTHY A. RINGEISEN

I, Timothy A. Ringeisen, declare and say as follows:

That I am an inventor named on U.S. Patent Application Serial No. 10/729,146, entitled "Compressed High Density Fibrous Polymers Suitable for Implant";

That I am named as an inventor or co-inventor on 4 issued U.S. Patents and 13 pending U.S. patent applications;

That my formal education consists of a Bachelor of Science degree in Biology from Gustavus Adolphus College, and a Master of Industrial Hygiene from University of Minnesota;

That the above-identified patent application is subject to an obligation of assignment to Kensey Nash Corporation, a Delaware corporation with facilities in Exton, Pennsylvania;

That I am employed by Kensey Nash Corporation at its Exton facility as a Director of Biomaterials Research;

That I have 7 years of experience with this company, and that I have 18 years of experience overall as a Biomaterials Engineer;

That I am familiar with U.S. Patent No. 5,158,574 to Stone, and with U. S. Patent Application Publication No US2002/0127270 A1 to Li et al.;

That I am familiar with the invention claimed in the above-identified USSN 10/729,146 patent application;

That the claimed invention relates to a compressed polymeric fibrous implant where the fibers are at least partially aligned and arrange themselves in the form of plates of aligned fibers;

That the partially aligned fibers of the instant invention may be prepared by charging a mixture featuring liquid, fibers and a lubricant into a mold, and compressing the mixture to remove fluid;

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That as compression commences, the fibers migrate through the remaining fluid and begin to organize themselves into a plurality of plates. The fibers tend to align within a given plate, but the plates themselves are not necessarily aligned with respect to one another. The or plates are defined by fluid planes. The fluid planes may not extend across the entire structure, but instead may exist as multiple fissures located randomly throughout the structure. Additional compression brings the plates of fibers into closer contact, allowing them to become locked into a compact anisotropic structure, although the material may be isotropic in two dimensions.

That Stone prepares a prosthetic, resorbable meniscus for implantation in a human knee, and in one embodiment thereof, he aligns fibers in a circumferential direction by rotating a mold as he places fibers in the mold, or by compressing fibers in a mold with a rotating piston.

That the circumferential orientation of the fibers in Stone is due to the rotation of the piston or mold, according to Stone himself;

That the rotation of the piston or mold disrupts any organization of fibers into plates;

That the compression process of the instant invention never features a rotation of a piston or of the mold during the compression step;

That the arrangement of fibers in the products of Stone and that of the instant invention is accordingly fundamentally different from one another;

That I purchased a commercially available product that I honestly and reasonably believe to correspond to the product disclosed in the Patent to Li;

That the SEM photomicrograph of Appendix A is of a cross-section of this material corresponding to the Li Patent showing the layers of oriented biopolymeric fibers as described in his specification;

That the SEM photomicrographs of Appendix B is of a cross-section of the material of the instant invention taken at three different magnifications; and

That I understand that all statements made herein (including statements made in the attachment documents) of my own knowledge are true and that statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Further, declarant sayeth not.

Timothy A. Ringeisen  
Timothy A. Ringeisen

09/09/08  
Date